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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,967	12/31/2001	Wilhelmus Evergardu Hennink	313632001000	8024

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,967	HENNINK ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 21-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time and amendment filed 01/07/04. Claims 1-17 and 21-26 are pending.

Claim Rejections - 35 USC § 112

1. All the claims were not rejected on the alleged grounds of indefiniteness. Claims 18-20 rejected under 35 U.S.C. 112, second paragraph. But the rejection of claims 18-20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because the said claims are canceled.

Claim Rejections - 35 USC § 102

2. Claims 1-5, 7-10 and 13 remain rejected under 35 U.S.C. 102(b) as being anticipated by Okihara et al. (J. Macromol. Sci. Phys. (1991) B30 (1 & 2)119-140, submitted on form PTO-1449).

Okihara discloses a stereocomplex mixture poly(L-lactide) and poly(D-lactide) and the mixture comprises equimolar amounts of the L- and D-lactide forms (abstract and page 120, paragraph 1). The mixture inherently forms hydrogel. Regarding instant claims 3-5, 8-10 and 13, the stereocomplex of Okihara would inherently have the instant property since the property of a composition cannot be separated from the composition.

Applicants argue that the stereocomplex of Okihara are crystalline and do not comprise water-soluble or water-dispersible polymers in aqueous system.

3. Applicants' arguments filed 01/07/2004 have been fully considered but they are not persuasive. The components of the stereocomplex of Okihara are poly(L-lactide) and poly(D-lactide) and these are the oligomers or co-oligomers that are recited in the depended claims and thus they ought to be water-soluble.

4. Claims 1-10, 14 and 21-2 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hennink et al. (WO 98/00170, cited on form PTO-1449); new claims 24-26 are included in this rejection.

Hennink discloses a biodegradable hydrogel that contains hydrolysable bonds and where the hydrogel consists of two interpenetrating polymer networks interconnecting to one another through hydrolysable spacers (abstract). In Hennink, (poly)glycolic acid and/or (poly)lactic acid spacers are introduced between polymerizable methacrylate groups and dextran (page 7, lines 24-27 and page 8). The hydrogel is prepared by a radical polymerization in the presence of tertiary amine and persulfate initiator (page 9, lines 14-23). Increasing degree of substitution (DS) yields a more cross-linked network (page 9, lines 31-34). Drugs are loaded onto the hydrogel during polymerization or cross-linking (page 10, lines 24 and 25). The hydrogel of Hennink are applied as microspheres of varying sizes (page 10, lines 26-34). See also examples 1-5 for preparation of hydrogels. The teachings of Hennink meet the limitations of the claims.

Applicants argue that Henniks hydrogel contains hydrolysable bonds consisting of two interpenetrating networks.

5. Applicants' arguments filed 01/07/2004 have been fully considered but they are not persuasive. The instant claims do not exclude hydrolysable bonds consisting of two interpenetrating networks.

Claim Rejections - 35 USC § 103

6. Claim 11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hennink et al. (WO 98/00170, cited on form PTO-1449).

Hennink clearly teaches the instant hydrogel composition. Hennink teaches that increasing degree of substitution (DS) yields a more cross-linked network (page 9, lines 31-34). Hennink does not teach a degree of substitution of 3-25 as recited in instant claim 11. There is no comparable example to demonstrate that a degree of substitution of 3-25 provides unusual results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a stereocomplex hydrogel that has appropriate degree of substitution since according to the teaching of Hennink degree of substitution is related to how cross-linked the polymer network is. One having ordinary skill in the art would have been motivated to prepare a stereocomplex hydrogel composition with a varying degree of substitution with the expectation of obtaining a hydrogel with the desired cross-linked network.

Applicants state that Hennink fails to teach or suggest claim 1 and therefore, claim 11, which depends on claim 1 is not taught by Hennink and that there is no motivation to modify intermolecularly cross-linked polymer.

7. Applicants' arguments filed 01/07/04 have been fully considered but they are not persuasive. The instant claims do not exclude hydrolysable bonds consisting of two interpenetrating networks and thus there ought not to be a motivation expected to modify intermolecularly cross-linked polymer.

8. Claim 12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Okihara et al. (J. Macromol. Sci. Phys. (1991) B30 (1 & 2)119-140, submitted on form PTO-1449).

Okihara teaches the stereocomplex hydrogel composition of the instant invention except that Okihara is silent on the length of the monomers. There is no comparable example to demonstrate that an average length of 7-15 monomers provided unusual results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a stereocomplex hydrogel composition that comprises any length monomers since Okihara appears to teach all lengths. One having ordinary skill in the art would have been motivated to take a mixture of lactides having the appropriate lengths with the expectation that a stereocomplex hydrogel will form.

Applicants argue that Okihara teaches crystalline complexes, which are not hydrogels and therefore there is no motivation to modify crystalline stereocomplex to teach hydrogels.

9. Applicants' arguments filed 01/07/04 have been fully considered but they are not persuasive. As stated above the composition of Okihara are inherently hydrogels because the monomers or oligomers of Okihara are the same as those recited in the dependent claims.

10. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Jong et al. (Macromolecules, 1998, 31:6397-6402, provided by applicants on form PTO-1449) in view of Brannon-Peppas (Int. J. Pharm, 1995, 116:1-9, provided by applicants on form PTO-1449).

De Jong discloses preparation of stereocomplexes homo- or copolymers of D- and L-lactides and further discloses that stereocomplex formation is also observed in blends of L-lactide/ε-caprolactone and D-lactide/ε-caprolactone (abstract and page 6397). Synthesis of the stereocomplex begins with preparing the oligomer in the presence (2-(methoxyethoxy)ethanol

(MEE)) initiator and stannous octoate catalyst (page 6399). De Jong does not teach incorporating active ingredient in the stereocomplex. However, Brannon-Peppas discloses that copolymers of polylactic acid are drug carriers (abstract). Regarding the sequence or preparing the drug containing hydrogel, selection of any order of the preparation steps in instant claims 15-17 is obvious in the absence of unexpected results showing that the order recited in the claims provides unusual results. Therefore, it would have been obvious to one of ordinary skill in the at the time the invention was made to include an active ingredient in the hydrogel composition of De Jong since Brannon-Peppas teaches that lactide hydrogels can be drug carriers. One having ordinary skill in the art would have been motivated to include active agents in the lactide hydrogel formulation of De Jong with the expectation that the stereocomplex lactide hydrogel would serve as a carrier.

11. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600